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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,029	04/14/2004	Mark B. Knudson	13033.4USC4	7478

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EXAMINER

GILBERT, SAMUEL G

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,029	KNUDSON ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2 papers</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 2/3/2005 and 7/8/2004 have been considered. The lined through references have not been considered because proper dates have not been provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Magovern(5,979,456).

Claims 1-4 - Magovern teaches a method of selecting and implanting a device into the pharyngeal wall to maintain the tissue in an open configuration. Applicant's attention is invited to figures 8-10 and column 7 line 51 through column 8 line 36. Further it is indicated that the structure can be formed by a mesh, column 3 lines 36-43. A mesh product would inherently have tissue in-growth areas. The mesh can be formed from the metal nitinol(NiTi) column 5 lines 48-56.

Claim 5 the method would inherently treat sleep apnea.

Claim 6 –the implant is not connected to a bony structure.

Claims 7-10 – elements –80a-, -80b-, -90a-, -90b-, -101-, -102-, -103-, -104- are metal implants which can be nitinol, column 5 lines 48-56. Further the elements can be formed in a mesh structure column 3 lines 36-43.

Claims 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Hubris(6,106,541).

Hubris teaches an implant –10- capable of being implanted in the pharyngeal wall) Implant –10- is formed with an internal skeleton –24- made from a metal, stainless steel, column 3 line 50, and an encasing sheath –26-.

Claim Rejections - 35 USC § 103

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubris (6,106,541) in view of Flexmedics(1989)

Claim 9 - Hubris teaches an implant –10- capable of being implanted in the pharyngeal wall) Implant –10- is formed with an internal skeleton –24- made from a metal, stainless steel, column 3 line 50, and an encasing sheath –26-. Hubris does not teach nitinol for the implant. Flexmedics teaches that nitinol provides a plurality of advantages over stainless steel including a superelastic property. It would have been

obvious to one of ordinary skill in the art at the time the invention was made to use nitinol in place of the stainless steel of Hubris to provide the implant with the ability to have its shape changed during implantation and then having the implant assume its desired shape after implantation without having to worry about changing the intended shape during implantation. This benefit is provided by the superelastic property of nitinol as shown by Flexmedics.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubris (6,106,541) as applied to claims 7 and 8 above further in view of Campbell et al (5,752,934).

Claim 10 - Hubris teaches an implant -10- which is capable of being implanted in pharyngeal tissue. The implant -10- is formed with an internal metal skeleton -24- and an encasing sheath -26-. The encasing sheath must be formed by a biocompatible material and sets forth polytetrafluoroethylene as an example. However the implant -10- does not include tissue in-growth areas. Campbell et al teaches a catheter including a balloon including an encasing sheath formed by a braid of polytetrafluoroethylene over the balloon for the purpose of providing chemical inertness and low coefficient of friction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a braided encasing as taught by Campbell as a substitution of functionally equivalent encasing elements since both are a biocompatible material encasings. The braided encasing would provide tissue in growth areas in the braid.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,742,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,626,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,601,585. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,431,174. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G. Gilbert
Primary Examiner
Art Unit 3736

sgg